

**PATEN** Attorney Docket No. UCSD-07017

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Maurizio Zanetti

Serial No.: Filed:

09/788,110

02/15/2001

Group No.: Not yet assigned Examiner: Not vet assigned

Entitled:

A Universal Vaccine and Method for Treating

Cancer Employing Telomerase Reverse

**Transcriptase** 

### TRANSMITTAL FOR INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents Washington, D.C. 20231

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Sir or Madam:

Enclosed please find an Information Disclosure Statement, Form PTO-1449 and copy of 68 references for filing in the U.S. Patent and Trademark Office.

In the event a petition is required in order to have this Information Disclosure Statement considered, please consider this a petition therefor.

The Commissioner is hereby authorized to charge any fee or credit overpayment related to this filing to our Deposit Account No. 08-1290. An originally executed duplicate of this transmittal is enclosed for this purpose.

Maha A. Hamdan

Signed on behalf of:

Registration No. 43,655

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 415.904.6500

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Sir or Madam:

The citations listed below, copies attached, may be material to the examination of the above-identified application, and are therefore submitted in compliance with the duty of disclosure defined in 37 C.F.R. §§ 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application.

The following patents are referred to in the body of the specification:

- US Patent No. 4,622,952 issued 11/18/86 to-Gordon;
- US Patent No. 5,658,234 issued 8/19/97 to Dunlavy;
- US Patent No. 6,106,829 to issued 8/22/00 to He *et al.*;

The following publications are referred to in the body of the specification:

- Mattes et al. (1983) "A Pigmentation-associated, Differentiation Antigen of Human Melanoma Defined by a Precipitating Antibody in Human Serum," Int. J. Cancer 32:717;
- Tai *et al.* (1983) "Glycoproteins as Differentiation Markers in Human Malignant Melanoma and Melanocytes," Cancer Res. 43:2773;

- Thomson et al. (1988) "Differentiation Antigens of Melanocytes and Melanoma: Analysis of Melanosome and Cell Surface Markers of Human Pigmented Cells with Monoclonal Antibodies," J. Invest. Dermatol. 90:459;
- Zakian (1995) "Telomeres: Beginning to Understand the End," Science 270:1601;
- Blackburn and Gall (1978) "A Tandemly Repeated Sequence at the Termini of the Extrachromosomal Ribosomal RNA Genes in *Tetrahymena*," J. Mol. Biol. 120:33;
- Oka et al. (1980) "Inverted terminal repeat sequence in the macronuclear DNA of Stylonychia pustulata," Gene 10:301;
- Klobutcher et al. (1981) "All gene-sized DNA molecules in four species of hypotrichs have the same terminal sequence and an unusual 3' terminus," Proc. Natl. Acad. Sci. 78:3015; and
- Wellinger et al. (1993) "Origin Activation and Formation of Single-Strand TG<sub>1-3</sub> Tails Occur Sequentially in Late S Phase on a Yeast Linear Plasmid," Mol. Cell. Biol. 13:4057.

Applicants have become aware of the following printed publication which may be material to the examination of this application and which are listed in alphabetical order:

- US Patent No. 5,635,188 issued 6/3/97 to Bystryn;
- US Patent No. 6,168,946 issued 1/2/01 to Houghton *et al.*;
- Minev *et al.* (2000) "Cytotoxic T cell immunity against telomerase reverse transcriptase in humans," Proc. Natl. Acad. Sci. USA 97:4796-4801;
- Vonderheide et al. (1999) "The Telomerase Catalytic Subunit Is a Widely Expressed Tumor-Associated Antigen Recognized by Cytotoxic T Lymphocytes," Immunity 10:673-679;
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- Greider (1994) "Mammalian teleomere dynamics: healing, fragmentation shortening and stabilization," Curr. Opin. Genet. Devel. 4:203-11;

- Counter et al. (1992) "Telomere shortening associated with chromosome instability is arrested in immortal cells which express telomerase activity,"
   EMBO J. 11:1921-29;
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- Weng *et al.* (1997) "Telomere lengthening and telomerase activation during human B cell differentiation," Proc. Natl. Acad. Sci. USA 94:10827-32;
- Lee *et al.* (1998) "Essential role of mouse telomerase in highly proliferative organs," Nature 392:569-74;
- Kim *et al.* (1994) "Specific Association of Human Telomerase Activity with Immortal Cells and Cancer," Science 266:2011-5;
- Meyerson et al. (1997) "hEST2, the Putative Human Telomerase Catalytic Subunit Gene, is Up-Regulated in Tumor Cells and during Immortalization," Cell 90:785-795;
- Bodnar *et al.* (1998) "Extension of Life-Span by Introduction of Telomerase into Normal Human Cells," Science 279:349-52;
- Rudolph *et al.* (1999) "Longevity, Stress Response, and Cancer in Aging Telomerase-Deficient Mice," Cell 96:701-12;
- Greenberg *et al.* (199) "Short Dysfunctional Telomeres Impair Tumorigenesis in the INK4a $^{\Delta 2/3}$  Cancer-Prone Mouse," Cell 97:515-25;
- Morales *et al.* (1999) "Absence of cancer-associated changes in human fibroblasts immortalized with telomerase," Nature Genetics 21:115-8;
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- Marx (1993) "How p53 Suppresses Cell Growth." Science 262:1644-5;
- Disis *et al.* (1997) "HER-2/neu Protein: A Target for Antigen-Specific Immunotherapy of Human Cancer," Adv. Cancer Res. 71:343-71;
- Walker et al. (1988) "HIV-1 Reverse Transcriptase Is a Target for Cytotoxic T
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- Schwartz (1990) "A Cell Culture Model for T Lymphocyte Clonal Anergy," Science 248:1349-56;
- Firat *et al.* (1999) "H-2 class I knockout, HLA-12.1-transgenic mice: a versatile animal model for preclinical evaluation of antitumor immunotherapeutic strategies," Eur. J. Immunol. 29:3112-21;
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- Quaranta *et al.* (1982) "A Recurrent Idiotype on Monoclonal Anti-Human Ia Antibodies," J. Exp. Med. 156:1551-6;
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  activity by an antibody antigenized with the RGD motif," EMBO J. 12:43754384;
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- Sykulev *et al.* (1996) "Evidence that a Single Peptide-MHC Complex on a Target Cell Can Elicit a Cytolytic T Cell Response," Immunity 4:565-71;
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  a "self" antigen induces autoimmune vitiligo and tumor cell destruction in mice:
  Requirement for CD4<sup>+</sup> T lymphocytes," Proc. Natl. Acad. Sci. USA 96:2982-7;
- Hu et al. (1993) "An Evulation of the Potential to Use Tumor-associated
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   Med. 177:1681-90;
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- Falk *et al.* (1991) "Allele-specific motifs revealed by sequencing of selfpeptides eluted from MHC molecules," Nature 351:290-6;
- Rotzschke *et al.* (1990) "Isolation and analysis of naturally processed viral peptides as recognized by cytotoxic T cells," <u>Nature 348:252-254</u>; and
- Schumacher *et al.* (1991) "Peptide selection by MHC class I molecules," Nature 350:703-6.

This Information Disclosure Statement under 37 C.F.R. §§ 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

Signed on behalf of:

Dated: November 27, 2002

Maha A. Hamdan <sup>L</sup> Registration No. 43,655

MEDLEN & CARROLL, LLP 101 Howard Street, Suite 350 San Francisco, California 94105 415.904.6500 DEC 0 5 5005

FORM PTO-1449 (Modified)

U.S. Department of Commerce Patent and Trademark Office

Attorney Docket No.: UCSD-07017

Applicant: Maurizio Zanetti

Serial No.: 09/788,110

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use Several Sheets If Necessary)					Filing Date: 02/15/01 Group Art Unit:				
37 CFR § 1.9	8(b))			ILC DATENT DO		···	Group Art On	H.:	
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Examiner Initials	Cite No.	Serial / Patent Number	Issue Date	Applicant / Patentee		Class	Subclass	Filing Date	
	1	4,622,952	11/18/86		Gordon				
	2	5,658,234	8/19/97		Dunlavy	-R	CEIV	ED	
	3	6,106,829	8/22/00		He et al.		)FC 0 3 20	A2	
	4	6,168,946	1/2/01	Ног	ighton et al.		A A 9 YA	96	
	5	5,635,188	6/3/97		Bystryn	TECH	GENTER 160	0/2900	
····	-	OTHER D	OCUMENTS (Inclu	ding Author, Title, I	Date, Relevant Pages, Pl	lace of Publication)			
	6 /	Mattes et al. (1983) Human Serum," Int.	"A Pigmentation-ass J. Cancer 32:717	ociated, Differentiati	on Antigen of Human M	Melànoma Defined	by a Precipitating	Antibody in	
	7 .1	Tai et al. (1983) "Glycoproteins as Differentiation Markers in Human Malignant Melanoma and Melanocytes," Cancer Res. 43:2773							
	8 /	Thomson et al. (1988) "Differentiation Antigens of Melanocytes and Melanoma: Analysis of Melanosome and Cell Surface Markers of Human Pigmented Cells with Monoclonal Antibodies," J. Invest. Dermatol. 90:459							
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	14	Minev et al. (2000) "Cytotoxic T cell immunity against telomerase reverse transcriptase in humans," Proc. Natl. Acad. Sci. USA 97:4796 4801							
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aminer:					Date Considered:				

FORM PTO-1449 U.S. Department of Commerce Attorney Docket No.: UCSD-02424 Serial No.: 08/723,052 (Modified) Patent and Trademark Office INFORMATION DISCLOSURE STATEMENT BY APPLICANT Applicant: Mario Chojkier et al. (Use Several Sheets If Necessary) Filing Date: 09/30/96 Group Art Unit: (37 CFR § 1.98(b)) OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication) 26 Bodnar et al. (1998) "Extension of Life-Span by Introduction of Telomerase into Normal Human Cells," Science 279:349-52 OIP 27 Rudolph et al. (1999) "Longevity, Stress Response, and Cancer in Aging Telomerase-Deficient Mice," Cell 96:701-12 *∙*2}8 Greenberg et al. (199) "Short Dysfunctional Telomeres Impair Tumorigenesis in the INK4a<sup>Δ2/3</sup> Cancer-Prone Mouse," Cell 97:515-25 28 Morales et al. (1999) "Absence of cancer-associated changes in human fibroblasts immortalized with telomerase," Nature Genetics 21:115-8 DEC 0 2 2002 Hahn et al. (1999) "Creation of human tumour cells with defined genetic elements," Nature 400:464-8 Broccoli et al. (1995) "Telomerase activity in normal and malignant hematopoietic cells," Proc. Natl. Acad. 3 RADEM 32 Shay et al. (1997) "A Survey of Telomerase Activity in Human Cancer," Eur. J. Cancer 33:787-91 DEC 0 3 2002 33 Kim (1997) "Clinical Implications of Telomerase in Cancer," Eur. J. Cancer 33:-781-6 34 Nakamura et al. (1997) "Telomerase Catalytic Subunit Homologs from Fission Yeast and Human," Science 35 Marx (1993) "How p53 Suppresses Cell Growth." Science 262:1644-5 36 Disis et al. (1997) "HER-2/neu Protein: A Target for Antigen-Specific Immunotherapy of Human Cancer," Adv. Cancer Res. 71:343-71 37 Walker et al. (1988) "HIV-1 Reverse Transcriptase Is a Target for Cytotoxic T Lymphocytes in Infected Individuals," Science 240:64-6 Schwartz (1990) "A Cell Culture Model for T Lymphocyte Clonal Anergy," Science 248:1349-56 38 Firat et al. (1999) "H-2 class I knockout, HLA-12.1-transgenic mice: a versatile animal model for preclinical evaluation of antitumor 39 immunotherapeutic strategies," Eur. J. Immunol. 29:3112-21 40 Lee (1990) in The HLA System, ed. Lee, J. (Springer-Verlag, NY), pp 141-178 41 Fernandez-Vina et al. (1992) "DNA Typing for HLA Class I Alleles, I. Subsets of HLA-A2 and of -A28," Human Immunol. 33:163-73 Krausa et al. (1995) "Genetic polymorphism within HLA-A\*02: significant allelic variation revealed in different populations," Tissue 42 Antigens 45:223-31; 43 Ruppert et al. (1993) "Prominent Role of Secondary Anchor Residues in Peptide Binding to HLA-A2.1 Molecules," Cell. 74:929-37; Parker et al. (1994) "Scheme for Ranking Potential HLA-A2 Binding Peptides Based on Independent Binding of Individual Peptide Side-44 Chains," J. Immunol. 152:163-75 Vitiello et al. (1991) "Analysis of the HLA-restricted Influenza-specific Cytotoxic T Lymphocyte Response in Transgenic Mice Carrying a 45 Chimeric Human-Mouse Class I Major Histocompatibility Complex," J. Exp. Med. 173:1007-15 Sette et al. (1994) "The Relationship Between Class I Binding Affinity and Immunogenicity of Potential Cytotoxic T Cell Epitopes," J. 46 Immunol. 153:5586-92 van der Burg et al. (1996) "Immunogenicity of Peptides Bound to MHC Class I Molecules Depends on the MHC-Peptide Complex 47 Stability," J. Immunol. 156:3308-14 48 Sommerfeld et al. (1996) "Telomerase Activity: A Prevalent Marker of Malignant Human Prostate Tissue," Cancer Res. 56:218-22 49 Hunt et al. (1992) "Characterization of Peptides Bound to the Class I MHC Molecule HLA-A2.1 by Mass Spectrometry," Science 1261-3 50 Quaranta et al. (1982) "A Recurrent Idiotype on Monoclonal Anti-Human Ia Antibodies," J. Exp. Med. 156:1551-6 Zanetti et al. (1993) "Expression of conformationally constrained adhesion peptide in an antibody CDR loop and inhibition of natural killer 51 cell cytotoxic activity by an antibody antigenized with the RGD motif," EMBO J. 12:4375-4384 52 -Hiyama et al. (1995) "Activation of Telomerase in Human Lymphocytes and Hematopoietic Progenitor Cells," J. Immunol. 155:3711-15 Pascolo et al. (1997) "HLA-A2.1-restricted Education and Cytolytic Activity of CD8<sup>+</sup> T Lymphocytes from β2 Microglobulin (β2m) HLA-53 A2.1 Monochain Transgenic H-2Db β2m Double Knockout Mice," J. Exp. Med. 185:2043-51 Doyle et al. (1985) "Markedly Decreased Expression of Class I Histocompatibility Antigens, Protein, and mRNA in Human Small-Cell Lung 54 Cancer," J. Exp. Med. 161:1135-51 Examiner: Date Considered: **EXAMINER:** Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney Docket No.: UCSD-02424	Serial No.: 08/723,052						
INFORMATIO	ON DISCLOSURE STATEMENT BY APPLICANT (Use Several Sheets If Necessary)	Applicant: Mario Chojkier et al.							
(37 CFR § 1.98(b))	(ose service sineres in recessary)	Filing Date: 09/30/96	Group Art Unit:						
OTHER DOCUMENTS (Including Author, Title, Date, Relevant Pages, Place of Publication)									
55 -	Momburg et al. (1986) "Loss of HLA-A,B,C and De Novo Expression of HLA-D in Colorectal Cancer," Int. J. Cancer 37:179-84								
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64 ,	Hu et al. (1993) "An Evulation of the Potential to Use Tumor-associated Antigens as Targets for Antitumor T Cell Therapy Using Transgenic Mice Expressing a Retroviral Tumor Antigen in Normal Lymphoid Tissues," J. Exp. Med. 177:1681-90								
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